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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,869	01/24/2002	Hiroshi Nagasawa	NAGASAWA=7	5352

1444 7590 04/21/2003

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

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DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,869

Applicant(s)

NAGASAWA, HIROSHI

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-4 in papers filed 10 March 2003 is acknowledged.

The traversal is on the grounds(s) that it would not be undue burden to examine the claims of groups I and II because the subject matter of Claim 5 (Group II) is sufficiently similar to the elected subject matter of Claims 1-4 (Group I). However, it is maintained that undue burden would be required to examine the claim of Group II along with claims of Group I as evidenced by the fact that the claims of Groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of inventions II. Specifically, a search of the subject matter of Group I encompasses a search of substrates, substrate configuration, probe carriers, probe carrier arrangement and probe carrier association with membranes and/or nonwoven fabric. In contrast, a search of the subject matter of Group II would encompass a search of detection systems, substrates, sample flow, sample flow speed, sample flow timing, and fluorescent detectors. As such, a search for the subject matter of Group I would not begin to encompass the search for the subject matter of Group II.

Applicant further argues that the inventions of Groups I and II are related as combination, subcombination and are not related as product and process of use as stated in the Restriction Requirement. The argument has been considered but is not found persuasive because Claim 5 (Group II) is drawn to a detection system adapted to flow a sample and detect an analyte. The claim does not recite that the system comprises the reaction probe chip of Claim 1 and further more does not recite that the system comprises the limitation of the

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reaction probe chip. Claim 5 merely recites a detection system adapted to flow a sample....through...a substrate which is interpreted as being drawn to a use of a substrate, which is one, and only one component of the reaction probe chip of Claim 1 (Group II). However, even if the inventions of Groups I and II were related as combination, subcombination MPEM § 806.05(c) states Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (detection system) as claimed does not require the particulars of the subcombination (reaction probe chip) as claimed because the detection system does not require a carrier filled into and held in the through-holes of the substrate and probe molecules different according to the through-holes. The subcombination has separate utility such as a solid support for binding probe-molecule binding partners followed by elution thereof.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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Specification

3. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are indefinite in Claim 1 for the recitation “the probe molecules are different according to the through-holes.” because “according to” is a non-specific relational phrase and therefore the relationship between the probe molecules and through-holes is undefined. It is suggested that Claim 1 be amended to define the relationship e.g. before “probe” insert “different” and after “are” insert “fixed to” and delete “according to the”.

Claim 4 is indefinite because the claim is drawn to a number of different and diverse probe molecules some of which are recited in the alternative (DNAs, RNAs, or PNAs) and some of which are recited as a Markush group (epitopes and enzymes). Therefore, it is unclear what group constitutes the probe molecules. It is suggested that Claim 4 be amended to clarify.

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if “wherein R is a material selected from the

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group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. (see MPEP, 2173.05(i).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehl et al (WO 98/08594, published 5 March 1998).

Regarding Claim 1, Mehl et al disclose a reaction probe chip comprising a substrate having a plurality of discrete regularly arranged through-holes and a carrier (nano-porous wafer) in the through-holes having probe molecules fixed thereto such that the probe molecules are different according to the through-holes (i.e. microparticles, page 5, line 26-page 6, line 7; page 8, line 33-page 9, line 15; and Claims 46-48).

Regarding Claim 2, Mehl et al disclose the reaction chip wherein the carrier having the probe molecules fixed thereto is a porous membrane and the membrane is pasted to the

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substrate so as to close the through holes i.e. the solution containing the carrier (microparticles) is applied to the through-hole (aperture) of the support whereupon solidification the through hole is closed (page 20, lines 10-17).

Regarding Claim 3, Mehl et al disclose the reaction chip wherein the carrier is a powder of porous glass (i.e. glass microparticles, page 19, lines 8-11, 17-18 and 21-22) and the carrier is bound to a porous membrane (i.e. microporous retainer, page 9, lines 4-14 and Claims 46-48) so as to close the through holes i.e. the solution containing the carrier is applied to the membrane whereupon it solidifies thereby closing the holes (page 20, lines 1-17 and Claims 46-48).

Regarding Claim 4, Mehl et al discloses the reaction chip wherein the probe molecules are selected from DNAs, RNAs, fragments thereof, oligonucleotides, antigens, antibodies, epitopes, proteins and functional sites (page 6, lines 2-7 and page 19, line 32-page 20, line 3).

8. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Düsterhöft et al (U.S. Patent No. 6,451,260 B1, filed 9 March 1999).

Regarding Claim 1, Düsterhöft et al disclose a reaction probe chip comprising a substrate having a plurality of discrete regularly arranged through-holes and a carrier (nanoporous wafer) in the through-holes having probe molecules fixed thereto such that the probe molecules are different according to the through-holes (i.e. microparticles, Column 3, lines 37-60; Column 5, lines 26-42; and Claim 21).

Regarding Claim 2, Düsterhöft et al disclose the reaction chip wherein the carrier having the probe molecules fixed thereto is a porous membrane and the membrane is pasted to

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the substrate so as to close the through holes i.e. the solution containing the carrier (microparticles) is applied to the through-hole (aperture) of the support whereupon solidification the through hole is closed (Column 12, lines 21-31).

Regarding Claim 3, Düsterhöft et al disclose the reaction chip wherein the carrier is a powder of porous glass (i.e. glass microparticles, Column 11, lines 41-45, 53-54 and 59) and the carrier is bound to a porous membrane (i.e. microporous retainer, Column 5, lines 39-42 and Claim 21) so as to close the through holes i.e. the solution containing the carrier is applied to the membrane whereupon it solidifies thereby closing the holes (Column 12, lines 21-31 and Claims 21-22).

Regarding Claim 4, Düsterhöft et al discloses the reaction chip wherein the probe molecules are selected from DNAs, RNAs, fragments thereof, oligonucleotides, antigens, antibodies, epitopes, proteins and functional sites (Column 3, lines 50-57 and Column 12, lines 8-12).

9. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Beattie (U.S. Patent No. 5,843, 767, issued 1 December 1998).

Regarding Claim 1, Beattie discloses a reaction probe chip comprising a substrate having a plurality of discrete regularly arranged through-holes and a carrier (nano-porous wafer) in the through-holes having probe molecules fixed thereto such that the probe molecules are different according to the through-holes (e.g. Example 11, Column 21, line 55-Column 22, line 18).

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Regarding Claim 4, Beattie discloses the reaction chip wherein the probe molecules are selected from DNAs, RNAs, fragments thereof, oligonucleotides, antigens, antibodies, epitopes, proteins and functional sites (Column 2, lines 21-30 and Column 8, lines 55-67).

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kedar et al (U.S. Patent No. 6,083,761, filed 1 December 1997).

Regarding Claim 1, Kedar et al disclose a reaction probe chip comprising a substrate having a plurality of discrete regularly arranged through-holes (i.e. capillary hole, Column 9, lines 3-14) and a carrier in the through-holes having probe molecules fixed thereto such that the probe molecules are different according to the through-holes (Column 4, lines 15-67; Column 6, lines 22-34; and Column 9, lines 45-67).

Regarding Claim 2, Kedar et al disclose the reaction chip wherein the carrier having the probe molecules fixed thereto is a porous membrane and the membrane is pasted to the substrate so as to close the through holes i.e. the through-hole is of a size such that upon filling the substrate with the carried, the hole is closed i.e. the fluid is retained (Column 4, line 59-Column 5, line 10 and Column 9, lines 3-14; 26-42; and 55-67).

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Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
April 17, 2003